K021055
page1

APR 2 9 2002

**510 (k) Summary**
[as required by 21 CFR 807.92]

**Date Prepared [21 CFR 807.92(a)(1)]**

March 28, 2002

**Submitter's Information [21 CFR 807.92(a)(1)]**

Joseph M. Azary III
C/o Azary Technologies LLC
P.O. Box 2156
Huntington, CT. 06484

Azary Technologies has received authorization to submit this 510(k) on behalf of the sponsor Busse Hospital Disposables Inc., 75 Arkay Drive, Hauppauge, NY 11788

**Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]**

The device trade names are: Busse Umbilical Cord Clamp Cutter

Common Name/Classification Name: Umbilical Cord Clamp Cutter

**Predicate Device [21 CFR 807.92(a)(3)]**

- Busse Posi-Grip Umbilical Cord Clamp K010835
- Precision Dynamics Corporation Umbilical Cord Clamp Cutter K994263
- Hollister Umbilical Cord Clamp Cutter K781548

**Description of the Device [21 CFR 807.92(a)(4)]**

The subject device is a cutter designed to safely cut the umbilical cord clamp. The device is composed of ABS (Acrylonitrile Butadiene Styrene) Doc 26720NT Natural resin with a stainless steel blade. The device does not make contact with the patient. The device is provided non-sterile and is labeled for single patient use. The subject device is packaged in a 3"x5" Glassine Bag and will be included in the dispenser box with the Busse Posi-Grip Umbilical Cord Clamps.

**Intended Use [21 CFR 807.92(a)(5)]**

The intended use is to cut the umbilical cord clamp off a newborn's umbilical cord.

**Technological Characteristics [21 CFR 807.92(a)(6)]**

The 510(k) is for the purpose of adding an umbilical cord clamp cutter to the dispenser box of the Busse Posi-Grip Umbilical Cord Clamp (K010835). The Umbilical Cord Clamp is purchased from DeRoyal Industries and is the same umbilical cord clamp cutter sold by Precision Dynamics Corporation (K994263) and is similar in design to the Hollister Umbilical Cord Clamp Cutter (K781548).

**Performance Data [21 CFR 807.92(b)(1)]**

Product qualification testing found the umbilical cord clamp cutter to function properly when tested with Busse Posi-Grip Umbilical Cord Clamps. The subject device cut the umbilical cord clamps without problem.

**Conclusion [21 CFR 807.92(b)(3)]**

The subject device is to be added to the dispenser box with Busse Posi-Grip Umbilical Cord Clamps. It is identical to the umbilical cord clamp cutter sold by Precision Dynamics Corporation and is similar in design to the Hollister umbilical cord clamp cutter.

The subject device does not make contact with the patient, is non-sterile and labeled for single patient use. The physician places the jaws over the hinge area of the umbilical cord clamp. Once properly located and engaged, pressure is applied to the cutter grips and the hinge is cut in half.

We conclude that the subject devices are as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2002

Busse Hospital Disposables, Inc.
% Mr. Joseph M. Azary
Azary Technologies™, LLC
P.O. Box 2156
HUNTINGTON CT 06484

Re: K021055
Trade/Device Name: Busse Umbilical Cord Clamp Cutter
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: 85 HFW
Dated: March 28, 2002
Received: April 1, 2002

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5 10(k) Number (if known): K021055

Device Name: Busse Hospital Disposables Inc. Umbilical Cord Clamp Cutter

Indications For Use: The intended use is to cut the umbilical cord clamp off a newborn's umbilical cord.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021055